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DEC 2 0 2011

510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Submitter:** Unimax Medical Systems Inc.

Address: 8F-2, No. 127, Lane 235, Pao Chiao Rd., Hsin Tien City, Taipei, Taiwan

Phone: 886-2-89191698

Fax: 886-2-89191528

Contact: Sophia Chiu

Establishment Registration Number: 3007791595

5.3 **Identification of the Device:**

Proprietary/Trade name:	Unimax Laparoscopic Instrument
Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Device Classification:	II
Regulation Number:	878.4400
Panel:	General & Plastic Surgery
Product Code:	GEI

5.4 **Identification of the Predicate Device:**

Predicate Device Name:	AED Monopolar Lap Accessories
Manufacturer:	National Advanced Eedoscopy Devices, INC.

510(k) Number or Clearance Information: K081503

5.5 **Intended Use and Indications for Use of the subject device.**

The Unimax Laparoscopic Instrument is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

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5.6 Device Description

The Unimax Laparoscopic Instrument includes Grasping Forceps, Monopolar Scissors, and Monopolar Probe/Electrodes. The devices are disposable, single use, individually packaged devices that are composed of biocompatible materials. Scissors and forceps have a handle with rotating wheel attached to an insulated shaft with different tips, which allows the shaft and tip to rotate. They include a male cautery connector when attached to standard monopolar cautery cables and their generators. Probes/Electrodes have an insulated shaft with a thermally conductive metal tip electrode. The proximal end of the shaft is attached to a handle made of an injection molded, medical grade plastic.

5.7 Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Unimax Laparoscopic Instrument. The safety tests were conducted in accordance with **IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995, IEC 60601-1-2: 2001 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)), IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3), ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals, ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity, ISO 10993-12 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials, and ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.**

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The comparative performance testing was conducted on the subject device and the predicate device including the items listed below:

- Drop Testing
- Bending Test
- Pulling Test
- Torque Test
- Jaw Clamping Test
- Blade Sharpness Test
- Arcing Test
- Charring Test
- Thermal Spread Test

All the test results demonstrate the performance of Unimax Laparoscopic Instrument meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Unimax Laparoscopic Instrument is as safe and effective as the predicate devices.

5.8 Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

5.9 Substantial Equivalence Determination

The Unimax Laparoscopic Instrument submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared AED Monopolar Lap Accessories which is the subject of K081503. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

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Item	Proposed Device (Unimax Medical Systems Inc. Laparoscopic Instrument)	Predicate Device (National Advanced Endoscopy Devices, Inc. AED Monopolar Lap Accessories)
Intended Use	The Unimax Laparoscopic Instrument is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.	AED Monopolar Lap Accessories are reusable devices (forceps and electrodes) intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation.
Consisted Instruments	- Standard insulated monopolar handles - Insulated Shafts - Class I inserts (forceps, scissors) - Electrodes	- Standard insulated monopolar handles - Insulated Shafts - Class I inserts (forceps, scissors) - Probes/Electrodes
Models	Grasping Forceps: - Straight grasping forceps - Babcock grasping forceps - Clinch grasping forceps - Maryland dissecting forceps - Rat tooth grasping forceps - Duckbill grasping forceps - Johan grasping forceps Scissors Probe/Electrode: - Monopolar J hook probe - Monopolar L hook probe - Monopolar Spatula probe	Grasping Forceps: - Graspers, with spoon - Babcock Grasping Forceps - Endo Clinch Forceps - Maryland Forceps - Cobra Style Toothed Grasper - Duckbill Forceps - Johan Grasping Forceps Scissors Probe/Electrode: - J hook - L hook
Dimension	5mm/33cm 5mm/26cm 5mm/45cm	5mm/33cm 5mm/26cm 5mm/45cm

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Sterilization	EO Sterility	EO Sterility
Safety standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 10993-7 ISO 11135-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 14937
Performance standards	No performance standards	No performance standards
Compared performance testing	Drop Testing Bending Test Pulling Test Torque Test Jaw Clamping Test Blade Sharpness Test Arcing Test Charring Test Thermal Spread Test	Drop Testing Bending Test Pulling Test Torque Test Jaw Clamping Test Blade Sharpness Test Arcing Test Charring Test Thermal Spread Test

5.10 Conclusion

After analyzing bench tests, electrical safety testing data, it can be concluded that Unimax Laparoscopic Instrument is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 20 2011

Unimax Medical Systems, Inc.
% AcmeBiotechs Co., Ltd.
Mr. Michael Lee
No. 45, Minshen Rd. Danshui Town
Taipei County
China (Taiwan) 251

Re: K103508
Trade/Device Name: Unimax Laparoscopic Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 16, 2011
Received: December 16, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Pitts

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Unimax Laparoscopic Instrument

Indications for Use:

The Unimax Laparoscopic Instrument is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103508